REMARKS

In response to the Final Action dated July 28, 2009, and subsequent to the filing of a Response under 37 C.F.R. §1.116 on October 21, 2009, Applicants respectfully submit the foregoing supplemental amendments to the specification and the claims.

Specifically, the specification has been amended to include the deposit information for the hybridomas that secrete monoclonal antibodies 16H2 and 20F8. The deposits were made on May 20, 2003 with ECACC, as evidenced by the attached ECACC documents stating that the deposits were accepted by ECACC as patent deposits in accordance with the Budapest Treaty of 1977.

Applicants further submit that all restrictions on availability of these hybridomas to the public will be irrevocably removed upon the granting of the patent based upon the captioned application and the hybridomas will remain permanently available for a term of at least 5 years after the most recent request for the furnishing of a sample, and in any case, for a period of at least 30 years after the date of deposit or for the enforceable life of the U.S. patent whichever is longer. In the event that the hybridomas become non-viable or are inadvertently destroyed, such will be replaced with viable hybridomas of the same taxonomic description.

Further, claims 18 and 23 have been amended to insert the accession numbers of the deposited hybridomas. Additionally, claim 18 has been amended to delete the language "mutant or variant thereof".

No new matter is introduced by the foregoing amendments.

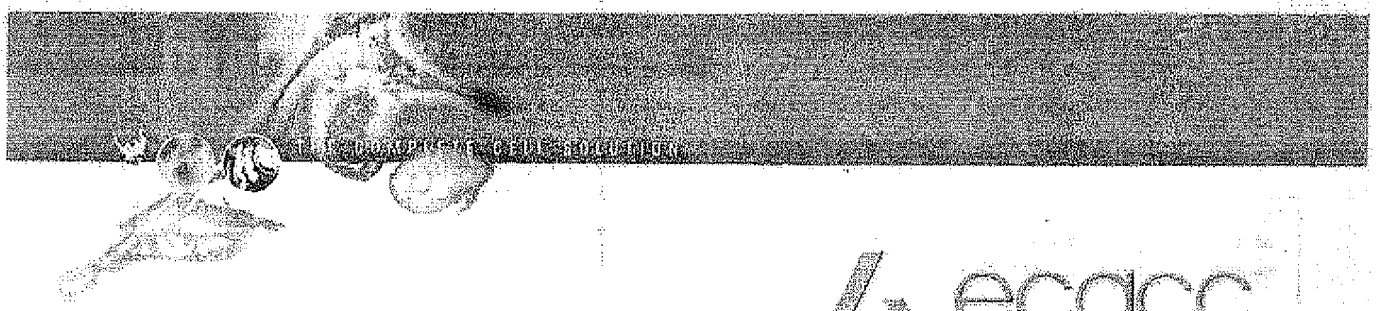
In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited. Should the Examiner believe that a telephone discussion will be helpful in resolving any outstanding issue, the Examiner is requested to contact the undersigned at the number indicated below.

Respectfully submitted,

Xiaochun Zhu
Registration No. 56,311

Scully, Scott, Murphy & Presser, P. C.
400 Garden City Plaza, Suite 300
Garden City, New York 11530
Telephone: (516) 742-4343
XZ:ab/dk

Enc.: ECACC deposit documents.



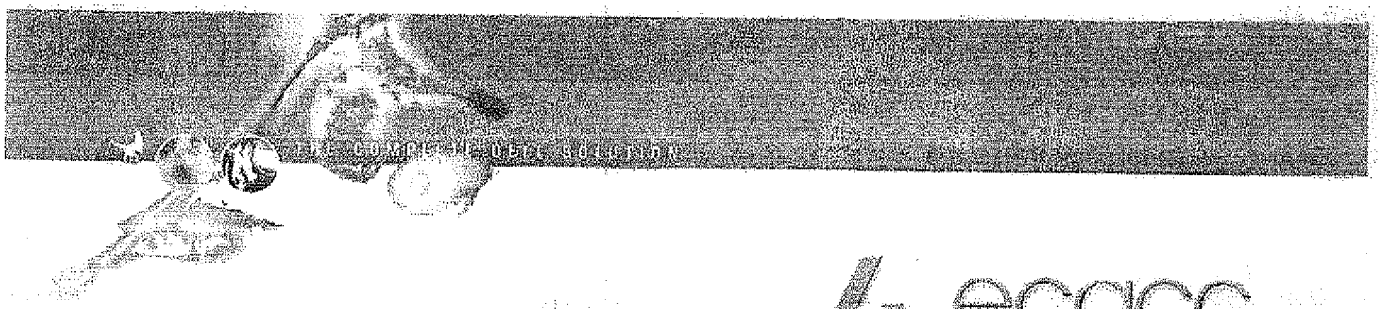
ecacc
European Collection of Cell Cultures

Centre for Applied Microbiology and Research and European Collection of Cell Cultures

This document certifies that
Hybridoma LM04 16H2.C1.B8
Deposit Reference 03052001
has been accepted as a patent deposit, in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on
20 May 2003

Dr D H Lewis
General Manager
ECACC

CAMR
European Collection of Cell Cultures, CAMR, Salisbury, Wiltshire SP4 0JG UK.
Tel: 44 (0) 1980 612512 Fax: 44 (0) 1980 611315 Email: ecacc@camr.org.uk Web Site: ecacc.org.uk



ecacc
European Collection of Cell Cultures

Centre for Applied Microbiology and Research and European Collection of Cell Cultures

This document certifies that
Hybridoma LM04 20F8.B2.C8
Deposit Reference 03052002
has been accepted as a patent deposit, in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on
20 May 2003

Dr D H Lewis
General Manager
ECACC

CAMR
European Collection of Cell Cultures, CAMR, Salisbury, Wiltshire SP4 0JG UK.
Tel: 44 (0) 1980 612512 Fax: 44 (0) 1980 611315 Email: ecacc@camr.org.uk Web Site: ecacc.org.uk

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

TO
DR L WILSON
WALTER & ELISA HALL INSTITUTE OF ME

POST OFFICE
ROYAL MELBOURNE HOSPITAL
PARKVILLE
VIC 3050
AUSTRALIA

NAME AND ADDRESS OF DEPOSITOR

INTERNATIONAL FORM

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the DEPOSITOR:
LM04 20F8.B2.C8

Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
03052002

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

[X] A scientific description

[ ] A proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above, which was received by it on 20 May 2003 (date of the original deposit)[1]

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and
A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)

IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis

Address: ECACC
CAMR
Porton Down
Salisbury SP4 0JG

Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized officials(s):

Date: 16/3/04

1 Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired

Form BP/4 (sole page)

1991

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO
DR L WILSON
WALTER & ELISA HALL INSTITUTE OF ME

POST OFFICE
ROYAL MELBOURNE HOSPITAL
PARKVILLE
VIC 3050
AUSTRALIA

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY OF STATEMENT IS ISSUED

VIABILITY STATEMENT
Issued pursant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: DR L WILSON WALTER & ELISA HALL INSTITUTE OF ME Address: POST OFFICE ROYAL MELBOURNE HOSPITAL PARKVILLE VIC 3050 AUSTRALIA	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: 03052002 Date of the deposit or of the transfer: 20 May 2003

III. VIABILITY STATEMENT

The viability of the microorganism identified under II above was tested on 20 May 2003 [2]. On that date, the said microorganism was

[X] [3] viable

[ ] [3] no longer viable

1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).

2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.

3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED [4]	
II. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr D H Lewis ECACC CAMR Address: Porton Down Salisbury Wiltshire SP4 0JG	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 16/3/04

4 Fill in if the information has been requested and if the results of the test were negative.

Form BP/9 (second and last page)

Certificate of Analysis

Product Description LM04 16H2.CL.B8
Lot Number 03/K/011

Test Description: Cell Count, Viability and confluency of cells on resuscitation from frozen.

Acceptance Criterion/Specification: were judged acceptable if they meet two of the following criteria:

- >70% viable cells
- >2 x 10^6 viable cells/ml
- confluent in 2 days

Date: 09/01/04
Result:

Viable Cell Count:	1.78 x 10^7 cells/ml
Percentage Viability:	41%
Confluent in:	Good Growth in 2 days

Test Description: The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.
SOP QC/MYCO/01

Acceptance Criterion/Specification: All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.
The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

Test Number: 28717
Date: 09/02/04
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Authorised by ..... A Long, **ECACC, Head of Quality** 16/2/04 **Date**

Certificate of Analysis

Product Description LM04 16H2.CL.B8
Lot Number 03/K/011

Test Description: Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.
SOP QC/MYCO/07

Acceptance Criterion/Specification: The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

Test Number: 28717
Date: 19/01/04
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Test Description: Sterility Testing of Cell Banks (SOP ECACC/048)

Acceptance Criterion/Specification: All positive controls (*Bacillis subtilus* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

Test Number: 28717
Date: 12/12/03
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Test Description: Monoclonal Antibody Isotyping.
SOP ECACC/019

Acceptance Criterion/Specification: The light chain and isotype detected match those expected. A band appears in the positive control region.

Test Number: 28717
Date: 22/01/04
Result:

Positive Control:	Positive
Expected Result:	Unknown
Test Result:	IgG2a

Authorised by ..... **ECACC, Head of Quality** ..... **Date**

Certificate of Analysis

Product Description LM04 20F8.B2.C8
Lot Number 03/K/012

Test Description: Cell Count, Viability and confluency of cells on resuscitation from frozen.

Acceptance Criterion/Specification: were judged acceptable if they meet two of the following criteria:

- >70% viable cells
- >2 x 10^6 viable cells/ml
- confluent in 2 days

Date: 09/01/04
Result:

Viable Cell Count:	1.02 x 10^7 cells/ml
Percentage Viability:	57%
Confluent in:	Good Growth in 2 days

Test Description: The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.
SOP QC/MYCO/01

Acceptance Criterion/Specification: All positive controls (*M. pneumoniae & M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.
The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

Test Number: 28716
Date: 09/02/04
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Authorised by ..... ECACC, Head of Quality..... **Date**

Certificate of Analysis

Product Description LM04 20F8.B2.C8
Lot Number 03/K/012

Test Description: Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.
SOP QC/MYCO/07

Acceptance Criterion/Specification: The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

Test Number: 28716
Date: 19/01/04
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Test Description: Sterility Testing of Cell Banks (SOP ECACC/048)

Acceptance Criterion/Specification: All positive controls (*Bacillis subtilus* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

Test Number: 28716
Date: 12/12/03
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Test Description: Monoclonal Antibody Isotyping.
SOP ECACC/019

Acceptance Criterion/Specification: The light chain and isotype detected match those expected. A band appears in the positive control region.

Test Number: 28716
Date: 22/01/04
Result:

Positive Control:	Positive
Expected Result:	Unknown
Test Result:	IgG2a

Authorised by ..... **ECACC, Head of Quality** ..... **Date**